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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/460,715	06/02/95	MACH	M 5552.0738-02

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EXAMINER

WORTMAN, D

ART UNIT

PAPER NUMBER

1648

29

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/460,715

Applicant(s)
Mach et al.

Examiner
Donna C. Wortman, Ph.D.

Art Unit
1648



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 11, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 7, 8, and 19-40 is/are pending in the application.

4a) Of the above, claim(s) 7 and 8 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 19-40 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 7, 8, and 19-40 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on January 11, 2001, has been entered.

Claims 19, 21, 24-36 and 39 were amended and new claim 40 was added in Paper No. 22. Claims 7 and 8 remain pending and withdrawn from consideration as drawn to a non-elected invention. Claims 19-40 are pending and under examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 24-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification discloses that, in HCMV strain Ad169, restriction fragment HindIII R comprises a nucleotide sequence that encodes pp28, but does not disclose which restriction fragments in

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other HCMV strains. It appears that the HindIII R fragment of other HCMV strains is not the same as the HindIII R fragment disclosed by applicant and does not contain sequences encoding pp28. See e.g., Pande et al., Virology 184, 762-767, 1991, of record (not prior art).

Applicant does not teach the location of the relevant sequences in any but the HCMV Ad169 strain and thus does not teach how to make and use the sequences as claimed. Amendment of the rejected claims to limit to strain Ad169 would overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 21, 24-36, 38, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite in reciting "said DNA molecule does not comprise an entire HindIII R fragment from the genome of human cytomegalovirus strain Ad169" because it is not clear what the intended DNA does comprise and what the claim encompasses. Does the claim encompass a DNA molecule that consists of the relevant HindIII R fragment, minus one base pair, for example? The metes and bounds of the claim remain unclear.

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Applicant has stated that the amended claim intends a DNA molecule that is a fragment of an entire HindIII R fragment; however, as set forth above, the boundaries of the intended DNA molecule are indefinite.

Claim 21 is indefinite because it recites "capable of bringing about the expression of ...". It is not clear what, if any, property of the claimed DNA molecule is intended or imparted by the recitation of "capable of ...", since it would appear that, in general, a DNA molecule that encodes a protein is capable of bringing about the expression of the protein it encodes.

Claim 25 is indefinite in reciting "wherein said DNA molecule is a fragment of the HindIII fragment that includes a DNA sequence which encodes pp28, or antigenic portions thereof that elicit antibodies that immunologically bind to pp28, and said DNA molecule does not comprise an entire HindIII R fragment from the genome of human cytomegalovirus." Claims 26-36 are similarly indefinite in reciting fragments of fragments that include a sequence, etc. Do these claims encompass a DNA molecule that consists of the relevant fragment, minus one base pair, for example? The metes and bounds of these claims remain unclear.

Claims 35 and 36 are indefinite in reciting "antigenic portions of said DNA sequence" since it is unclear what is intended by an antigenic DNA sequence.

Claims 35, 36, 37, and 39 are confusing since each recites a particular restriction fragment that "encodes pp28," but it appears that none of the restriction fragments recited in claims 35, 36, 37 and 39 in fact encode a portion of, rather than the entire, pp28.

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Claim 40 is indefinite in reciting "which hybridizes to the 1.3 kB RNA depicted in Figure 1 or its complement." Since any number of nucleotide sequences of varying lengths are capable of hybridizing to a given RNA sequence under at least some hybridization conditions and stringencies, the metes and bounds of claim 40 cannot be unambiguously determined.

Claim 40 is further indefinite in reciting "which hybridizes to the 1.3 kB RNA depicted in Figure 1 or its complement," because, while Figure 1 depicts a single RNA indicated by an arrow, there is no indication of molecular weight in Figure 1; consequently "1.3 kB" lacks antecedent support in Figure 1. Applicant must either amend the claim to delete "1.3 kB" if Figure 1 is referred to in the claim, or amend Figure 1 to include "1.3 kB" if appropriate. Applicant is cautioned against the introduction of new matter in amending the claim and/or the figure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Fleckenstein et al. (Gene 18:39-46, 1982), of record. Fleckenstein, as cited in Applicant's specification at page 3, lines 14-26, discloses cosmid clones containing HCMV strain Ad169 restriction fragments that

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cover the entire genome (see, e.g., Fig. 2 and Fig. 3) necessarily including portions that hybridize with the RNA shown in Fig. 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:00 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1648, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.



Donna C. Wortman, Ph.D.
Primary Examiner

April 23, 2001